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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,923	DOBIE ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17-20,22,23,26,27,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 21, 24-25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 2-16, 21, and 26-30 in the reply filed on 8/20/04 is acknowledged. The traversal is on the ground(s) that examination of inventions I-IV, as set forth in the restriction requirement mailed 7/20/04 would not constitute an undue burden because search of the prior art for invention would identify prior art of the other inventions (pg. 4, 3rd paragraph). However, contrary to Applicant's assertion, search of any of inventions I-IV together would impose a serious search burden. In the instant case, prior art searches of an oligonucleotide sequence and a method of using said oligonucleotide sequence are not coextensive. Search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular method steps of inventions II-IV not required for the search of invention I. These searches would then require subsequent in-depth analysis of all relevant prior art literature and sequence references, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV together.

Applicants also note, on page 5, 2nd paragraph, that they were unable to locate a requirement for Applicant to specifically elect a specific target region. Applicant's attention is drawn to section 8, page 8, lines 7-9 of the requirement for restriction mailed 7/20/04 wherein it is set forth that Applicant is required to identify which of claims 26-30 (each drawn to a compound that targets a particular region of a nucleic acid molecule

encoding ACE2), corresponds to the elected SEQ ID NO: and the subsequent paragraph which sets forth that applicant is required to elect one (1) oligonucleotide that corresponds to the target region claimed. It is noted herein that applicant has done exactly this in the communication filed 8/20/04, by electing SEQ ID NO: 36 and pointing out that the oligonucleotide that is SEQ ID NO: 36 targets the coding region of ACE2.

Applicant also asserts, on page 7, lines 1-3, that the restriction requirement the Office has levied against claims 20, 24 and 25 should instead be a species election. This is not found persuasive because, despite Applicant's assertions on page 7, 2nd paragraph, that the claimed sequences are related species, the nucleotide sequences listed in claims 20, 25 and 26 are subject to an additional restriction since these claims are not considered to be a proper genus/Markush for the reasons set forth in the requirement for restriction, section 8. In regards to improper Markush-type groupings, Applicant's attention is directed to MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS which states: If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In

re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicant also argues that the Commissioner has authorized up to has authorized a search of up to 10 unrelated nucleotide sequences and that because the sequences are related at least 10 sequences should be examined (pg 7, 3rd paragraph) and that the Office has failed to provide any explanation why one is a reasonable number (of sequences to be searched) and in which circumstances would a reasonable number be closer to 10. However, it is respectfully pointed out to Applicant that one (1) is encompassed by "up to 10" and that an explanation of why one is a reasonable number is set forth in section 8 of the prior Office Action wherein it describes how search of more than a single sequence would constitute an undue burden in terms of search and examination. Applicant is also advised herein that the circumstances in which a reasonable number (of sequences to be searched) would be closer to 10 would be determined on the merits, on a case by case basis.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

2. Claims 1-30 are pending in this application. Claims 17-20, 22-23, 26-27 and 29-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/04.

Priority

3. This application claims no benefit of priority from any earlier filed application. Therefore the benefit of priority of this application is considered to be the instant filing date, 3/10/2004.

Information Disclosure Statement

4. The information disclosure statement (IDS, PTO-1449) filed 3/10/04 contains multiple listings for references AA, and AB. Applicants attention is drawn to page 3 of the instant IDS where Applicant's AA in reference to U.S. patent 6,194, 556 is now designated AP, Applicant's AB in reference to U.S. Patent 6,610,497 is now designated AQ and Applicant's AO reference is now designated AR.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 (and claims 2-16, 21, 24-25 and 28, which depend directly or indirectly from claim 1) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "wherein said compound inhibits the

expression of ACE2 mRNA by at least 10%. In the instant case, the metes and bounds of a compound that inhibits the expression of ACE2 mRNA by at least 10% cannot be determined. One of skill in the art cannot determine, from what is claimed, under what conditions a compound would inhibit the expression of ACE2 mRNA by at least 10% because, as recognized by the state of the art, the conditions under which a compound can be used to inhibit gene expression are highly variable and can have a significant influence on the level of expression that is inhibited, Therefore, Applicant has not particularly pointed out or distinctly claimed the subject matter of their invention.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9, 13-16, 21, 24-25 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-16, 21, 24-25 and 28 are all drawn to an antisense compound 8-80 nucleobases in length that are at least 70% complementary (or at least 80%, 90%, 95% or 99% complementary: claims 9-12 respectively) to a nucleic acid molecule encoding ACE2 that inhibits the expression of ACE2 mRNA by at least 10%. These claims read

broadly on a vast number of antisense compounds that are at least 70% complementary to any portion of any nucleic acid molecule (including at least, genomic coding sequence, pre-mRNA, mature mRNA, transcript variants and alleles) in any organism that encodes ACE2. One of skill in the art, however, cannot envision the particular structure of an antisense compound that can be 70% or 80% or 90% or 95% or even 99% complementary to any region of any nucleic acid encoding any ACE2 that would correspond with the function of being an antisense oligonucleotide that inhibits the expression of ACE2 mRNA by at least 10%, commensurate with the breadth of the broad genus of antisense oligonucleotides as claimed.

The disclosure of the specification provides examples antisense oligonucleotide species of the invention that are 100% complementary to a particular nucleic acid molecule (human ACE2 RNA, pg. 69 paragraph bridging to pg. 70, specification as filed) encoding a particular human ACE2. The specification does not disclose a representative number of species of the broad genus of ACE2 nucleic acids as claimed and provides no guidance as to how one of skill in the art would know the structure of additional species of the invention based on the specification as filed. The specification, therefore, does not provide an adequate written description of the genus of antisense compound as claimed, which would indicate that applicant was in possession of said genus. The specification does not provide or point to a specific structure of an antisense compound as exemplified, which could be 70% or 80% or 90% or 95% or even 99% complementary to any region of any nucleic acid encoding ACE2, that corresponds with the function of being an antisense compound as claimed. The

specification does not disclose any distinguishing identifying characteristics of the genus of antisense compounds which could be 70% or 80% or 90% or 95% or even 99% complementary to any region of any nucleic acid encoding ACE2, that would indicate that applicant was in possession of this broadly claimed genus. Additionally, the disclosure of the specification provides no specific guidance as to how one skilled in the art might be reasonably led to a particular species of the invention that would function commensurate with the scope what is now claimed, such that the invention would be complete and ready for patenting.

Vas-Cath Inc. v. Mahurkar, 19USPQ2nd 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed (see page 1117). Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the

invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.").

Therefore, Applicant has not provided adequate written description of their invention because Applicant has provided "merely a wish or a plan for obtaining the chemical invention claimed" and has not shown how their invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that

show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. What, in particular, is the structure of an antisense compound which could be 70% or 80% or 90% or 95% or even 99% complementary to any region of any nucleic acid encoding ACE2, that corresponds with the function of inhibiting the expression of ACE2 mRNA by at least 10%, for example?

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-13, 15-16, 21 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Acton et al. (U.S. Patent 6,194,556; Ref. AO, USPTO-1449, 3/10/04, instant application). Claims 1-13, 15-16, 21 and 28 are drawn to an antisense compound 8-80 nucleobases in length targeted to a nucleic acid molecule encoding ACE2, wherein said compound is at least 70% complementary (claim 1) or 80% complementary (claim 9) or 90% complementary (claim 10) or 95% complementary (claim 11) or 99% complementary (claim 12) to a nucleic acid encoding ACE2 wherein said compound can comprise 12-50 nucleobases (claim 2) or 15-30 nucleobases (claim 3) wherein said compound can comprise an oligonucleotide (claim 4) wherein said

oligonucleotide can be DNA or RNA or chimeric (claims 5-7 respectively) wherein at least a portion of said oligonucleotide hybridizes with RNA to form an oligonucleotide-RNA duplex (claim 8). The antisense compound of claim 1 has at least one modified internucleoside linkage, sugar moiety or nucleobase (claim 13) wherein said compound has at least one 2'-methoxyethyl sugar moiety (claim 14) wherein said compound has at least one phosphorothioate internucleoside linkage (claim 15) wherein said compound has at least one 5-methylcytosine.

Acton et al. disclose antisense oligonucleotides targeted to ACE2 (column 23, section 4.3.2) and a particular antisense oligonucleotide that is SEQ ID NO: 13 that is 27 nucleobases in length that is 100% complementary (which is at least 70%, 80%, 90%, 95% and 99% complementary) to the coding region of human ACE2 (bases 1550-1576). Acton et al. disclose that the antisense oligonucleotides of their invention can be RNA or DNA oligonucleotides (column 24, lines 25-27) that can be targeted to the coding region of ACE2 (column 24, lines 53-56), that can be chimeric (column 25, line 11; column 26, line 11) that can comprise backbone, sugar moiety and nucleobase modifications (column 25, lines 12-14) wherein the backbone modification can be a phosphorothioate internucleoside linkage (column 24, line 67) wherein said oligonucleotide can comprise a 5-methylcytosine (column 25, line 41). Acton et al. disclose kits of their invention that can comprise an antisense oligonucleotide of their invention (column 5, lines 38-44; column 51, lines 19-22, column 64, lines 3-9). Absent evidence to the contrary, the prior art antisense compound of Acton et al. would inhibit expression of ACE2 mRNA by at least 10%, particularly in light of the previous

rejection under 112 2nd paragraph which indicates that the conditions under which an antisense compound of the instant invention would inhibit the expression of ACE2 mRNA are not particularly pointed out or distinctly claimed. Therefore, Acton et al. anticipate each and every aspect of the instant invention as claimed.

10. Claims 1-13, 15-16, 21 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Acton et al. (U.S. Patent 6, 610,497; Ref. AP, USPTO-1449, 3/10/04, instant application). The invention as claimed in claims 1-13, 15-16, 21 and 28 is outlined in a previous rejection.

Acton et al. disclose antisense oligonucleotides targeted to ACE2 (column 27, section 4.3.2) and a particular antisense oligonucleotide that is SEQ ID NO: 13 that is 27 nucleobases in length that is 100% complementary (which is at least 70%, 80%, 90%, 95% and 99% complementary) to the coding region of human ACE2 (bases 1550-1576). Acton et al. disclose that the antisense oligonucleotides of their invention can be RNA or DNA oligonucleotides (column 28, line 25) that can be targeted to the coding region of ACE2 (column 28, lines 2-5), that can be chimeric (column 28, lines 25-26; column 29, line 23) that can comprise backbone, sugar moiety and nucleobase modifications (column 28, line 28) wherein the backbone modification can be a phosphorothioate internucleoside linkage (column 29, line 12) wherein said oligonucleotide can comprise a 5-methylcytosine (column 28, line 54). Acton et al. disclose kits of their invention that can comprise an antisense oligonucleotide of their invention (column 5, lines 53-59; column 69, lines 55-60. Absent evidence to the

contrary, the prior art antisense compound of Acton et al. would inhibit expression of ACE2 mRNA by at least 10%, particularly in light of the previous rejection under 112 2nd paragraph which indicates that the conditions under which an antisense compound of the instant invention would inhibit the expression of ACE2 mRNA are not particularly pointed out or distinctly claimed. Therefore, Acton et al. anticipate each and every aspect of the instant invention as claimed.

Claim Rejections - 35 USC § 102 or 35 USC § 103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-8, 13-16, 21, 24 and 28 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Monia et al. (U.S. Patent 6,080,546). The invention as claimed in claims 1-8, 13-16, 21and 28 is outlined in a previous rejection. Claim 24 is drawn to the antisense compound of claim 1 wherein said compound comprises at least an 8-nucleobase portion of SEQ ID NO: 36 (the subject matter of the group elected). Monia et al. disclose antisense compounds that include SEQ ID NO: 34 that is an antisense oligonucleotide that is 20 nucleobases in length that is 75% complementary to a nucleic acid molecule encoding ACE2 that comprises at least an 8 nucleobase portion of instant SEQ ID NO: 36 (the prior art oligonucleotide

SEQ ID NO: 34 is completely complementary to positions 1-10 of instant SEQ ID NO: 36, at least)(column 61, about ½ way down and Table 2, in particular), that is targeted to the coding region of ACE2 (in being complementary to the same region as instant SEQ ID NO: 36), wherein said oligonucleotide can be RNA, DNA (column 5, 19-21) or chimeric oligonucleotides (column 9, lines 59-62; SEQ ID NO: 34 in Table 2) that has at least one modified sugar moiety that is a 2'-O-methoxyethyl sugar moiety (SEQ ID NO: 34 in Table 2) and at least one phosphorothioate backbone modification (SEQ ID NO: 34 in Table 2) wherein at least 1 cytosine is a 5-methylcytosine (example 16 and SEQ ID NO: 34 in Table 2). Monia et al. also disclose kits comprising the antisense compounds of their invention (column 11, lines 62-64).

Furthermore, since the prior art antisense compound meets all the structural limitations of the claims, the prior art antisense compound comprises an antisense compound 8-80 nucleobases in length targeted to a nucleic acid molecule encoding ACE2, wherein said compound is at least 70% complementary to a nucleic acid encoding ACE2. Absent evidence to the contrary, the prior art antisense compound of Monia et al. would inhibit expression of ACE2 mRNA by at least 10%, particularly in light of the previous rejection under 112 2nd paragraph which indicates that the conditions under which an antisense compound of the instant invention would inhibit the expression of ACE2 mRNA are not particularly pointed out or distinctly claimed. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the

examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Monia et al. (U.S. Patent 6,080,546).

Conclusion

13. No claims in the instant application are in condition for allowance. Claim 25, the elected subject matter of which is drawn to an antisense compound that has the sequence of SEQ ID NO: 36, is free of the prior art searched.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba

SEAN McGARRY
PRIMARY EXAMINER
1635